American Water Works Association
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October 21, 2016

SUBMITTED VIA E-MAIL

Versar, Inc.
ATTN: David Bottimore
6850 Versar Center
Springfield, VA 22151

RE: Request for Comment on Draft Peer Review Charge for Perchlorate (81 FR 67347; EPA-HQ-OW-2016-0439)

Dear Mr. Bottimore:

The American Water Works Association (AWWA) appreciates the opportunity to review and comment on the draft charges questions prepared for the perchlorate peer review panel. In reviewing the draft charge questions, we believe there are some revisions that would benefit the review process. The following revisions, ***bold italics***, and ~~strikeouts~~ where appropriate, are recommended for further consideration by the agency.

Amend Charge Question #1

Please comment on the following aspects of the BBDR model structure and integration of the submodels for iodide/thyroid hormones and perchlorate for each of the life stages of focus (i.e., lactating mother, breast-fed infant, and bottle-fed infant):

A. Does the developed model structure adequately and accurately describe the physiology and kinetics of iodine, thyroid hormones, and perchlorate during different life stages specified above? Please specifically note the strengths and weaknesses of the model structure for each life stage.
B. Are the physiological and kinetic parameters for iodine, thyroid hormones, and perchlorate for these life stages supported by the published sources for those parameters or data used to identify parameters via calibration? Please identify any critical data gaps or additional data on these model parameters.
C. Does the body up regulate the production of thyroid sodium-iodine symporters in the area of hypothyroxinemia prior to the stimulation of TSH? If so, how might this up regulation affect the modeling results.

Amend Charge Question #5

Given the lack of a specific quantitative clinical definition of hypothyroxinemia for the specific life stages evaluated (pregnant mothers, infants and lactating mothers) and that reference intervals of thyroid hormones reported in the literature are influenced by many factors (life stage differences, analytical method used, laboratory utilized, ethnicity, iodide nutrition, population size etc.), EPA developed a normalization procedure to derive hypothyroxinemia reference ranges.

A. Please comment on ***whether*** the ***development of this*** hypothyroxinemia reference range~~s~~ ***is consistent with EPA's definition of critical effect, that is the first adverse effect or its known precursor (singular), as dose rate increases. Might a different effect such as changes to TSH be a more appropriate critical effect? If the former is*** ~~on the~~ ***more appropriate,*** then is this particular ***hypothyroxinemia*** range derived for pregnant mothers, fetuses, lactating mothers, breast-fed infants and bottle-fed infants ***appropriate***.

B. Based on the perchlorate dose level at which each life stage is predicted to become hypothyroxinemic (for a given iodine ingestion rate), it appears that the lactating mother is much more sensitive than the breast-fed infant for PND 30-90. In part this occurs because breast feeding reduces the iodide available for the maternal thyroid. Is this prediction biologically realistic ***and clinically relevant,*** and if so, should the subsequent analysis also consider the lactating mother as a life-stage of concern for MCLG derivation?

Should you have questions or would like to discuss this matter, please contact me (tmehan@awwa.org) or Kevin Morley (kmorley@awwa.org).

Yours Sincerely,

G. Tracy Mehan, III
Executive Director – Government Affairs

cc: Peter Grevatt – EPA, OGWDW